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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,050	12/09/2003	Edward H. Overstreet	AB-389U	6749
23845	7590	06/30/2006	EXAMINER FLORY, CHRISTOPHER A	
ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 06/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/731,050

Applicant(s)

OVERSTREET ET AL.

Examiner

Christopher A. Flory

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3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-15, 17-22 and 24-26 is/are rejected.
- 7) ☒ Claim(s) 7-9, 16 and 23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/27/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because it exceeds the 150-word limit. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 10-15, 17-21, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Crosby et al. (US Patent 4,532,930).

Regarding claims 1-3 and 13-15, Crosby et al. discloses a method for correcting pitch allocation in a cochlear implant system comprising generating a reference signal and a probe signal and applying the reference and probe signals to appropriate electrodes in the cochlear implant system (column 46, lines 1-10); shifting the location where the probe or reference signal is applied until the two signals match (column 44, lines 7-13; column 46, lines 10-28); and using this relationship to generate a frequency map usable by the cochlear implant system to apply stimulus signals to the correct locations (column 44, lines 14-20; column 46, lines 29-53); further including generating additional reference and probe signals to augment the frequency map (column 46, lines 18-23); further including adjusting the stimulation parameters to obtain the best possible match, wherein the parameters include pulse amplitude and pulse width (column 18, line 38 through column 19, line 10).

Regarding claims 10-12, 17-20, and 25-26, Crosby et al. discloses a method wherein the probe signal has a known speech sound relationship with the reference signal (column 43, line 66 through column 44, line 25); wherein the probe and reference signals comprise either a F_0/F_1 vowel formant or a known consonant sound relationship

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(column 26, line 56 through column 28, line 35; column 29, line 18 through column 30, line 40).

Regarding claim 21, Crosby et al. shows a cochlear implant system (Figs. 2 and 3) comprising an implantable pulse generator (Fig. 2, receiver-stimulator unit 3); an electrode array having a multiplicity of electrodes (Fig. 3, electrode array 21); means for generating and applying a reference signal (Fig. 3, diagnostic and programming unit (DPU) 12); means for generating and applying a probe signal (DPU 12); means for determining when the probe signal matches the reference signal (column 46, lines 11-23); means for shifting the location where the signals are applied (Fig. 2, DPU 12 controls delivery of stimulation to electrode array 1); means for generating a frequency map (column 44, lines 14-20); and a means for using the frequency map to apply stimulus signals to correct locations within the cochlea (column 44, lines 21-27).

Regarding claim 24, Crosby et al. discloses a means for recognizing when the probe signal is in tune with the reference signal (column 46, lines 20-21). The reference signal and probe signal can be considered "in tune" when one signal is determined to be of a lower or higher pitch by the patient. "In tune" constitutes personal preference of the patient, and therefore constitutes an arbitrary, preferential measurement that does not patentably distinguish over the prior art.

It is noted that the "means for" language contained in claims 21-26 constitute an invocation of 35 U.S.C. 112, 6th paragraph.

5. Claims 1-3, 10, 13-15, 17-21, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Faltys et al. (US Patent 5,626,629).

Regarding claims 1-3, Faltys et al. discloses a method for correcting pitch allocation in a cochlear implant system comprising generating a reference signal and a probe signal and applying the reference and probe signals to appropriate electrodes in the cochlear implant system (column 16, lines 52-63); shifting the location where the probe or reference signal is applied until the two signals match (column 16, line 63 through column 17, line 15); and using this relationship to generate a frequency map usable by the cochlear implant system to apply stimulus signals to the correct locations (Fig. 5, specifically subdivided figures C-J and N sufficiently demonstrate the use of a frequency mapping function in the disclosed system); further including generating additional reference and probe signals to augment the frequency map (column 17, lines 11-15); further including adjusting the stimulation parameters to obtain the best possible match, wherein the parameters include pulse amplitude and pulse width (column 17, lines 2-10 and 35-58; column 18, lines 41-60).

Regarding claim 10, Faltys et al. discloses a method wherein the probe signal has a known speech sound relationship with the reference signal (column 17, line 15 through column 18, line 23).

Regarding claims 13-15, Faltys et al. discloses a method for correcting frequency allocation in a neurostimulation system (column 4, lines 10-15; column 10, lines 18-25) comprising shifting the location where a stimulus is applied until a desired criteria is achieved (column 16, lines 35-52; column 18, lines 24-40); controlling the temporal waveform structure of the applied stimulus (column 9, lines 46-61; column 10, lines 18-53); and further including applying a reference stimulus and a probe stimulus, wherein a

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fixed interval relationship exists between the stimuli and wherein the desired criteria comprises achieving a match between the reference signal and the probe signal (column 16, line 52 through column 17, line 15).

Further regarding claim 14, it is noted that sequential stimulation of the linear electrode array in order to properly order the electrode frequencies in Faltys et al. satisfies the clause "shifting the location where the stimulus is applied," and that the patient hearing a sensation that either sequentially increases or decreases in pitch satisfies the clause "until a desired criteria is achieved."

Further regarding claim 15, it is noted that a fixed interval relationship between the reference and probe stimuli of Faltys et al. arises from the reference and target channels representing adjacent electrodes, which fixes the relationship both spatially and tonically due to the fixed positioning of the electrodes within the implanted device.

Regarding claims 17-20, Faltys et al. further discloses a method wherein the fixed interval relationship between the reference signal and probe signal comprises a known speech sound relationship, where the speech sound relationship comprises a vowel formant, consonant sound, or tonal sequence relationship (column 17, line 15 through column 18, line 23). In this method, the audiologist speaks into the microphone of the implanted device and the audio spectrum of his speech is analyzed by frequency band and displayed on a screen. This display can be considered the reference signal. This audio spectrum, being based on normal speech, inherently includes segments representing vowel formants, consonant sounds, and tonally related sequences. Characteristics of bottomline amplitude and individual channel gains (representing

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weighting of specific frequency bands) can be adjusted either by the audiologist or the patient, and the speech stimulus (i.e. the probe stimulus) repeated until the patient perceives a best “sounding” result.

Regarding claim 21, Faltys et al. shows a cochlear implant system (Fig. 1) comprising an implantable pulse generator (implantable cochlear stimulator 46); an electrode array having a multiplicity of electrodes (electrode array 50); means for generating and applying a reference signal (programmer unit 14); means for generating and applying a probe signal (programmer unit 14); means for determining when the probe signal matches the reference signal (Fig. 2, user response to sweep function, balance function, and audio spectrum analyzer tests); means for shifting the location where the signals are applied (programmer unit 14 controls delivery of stimulation to electrode array 50); means for generating a frequency map (programmer unit 14; also Fig. 5 shows several displays that constitute a frequency map); and a means for using the frequency map to apply stimulus signals to correct locations within the cochlea (ICS 46).

Regarding claim 24, Faltys et al. discloses a means for recognizing when the probe signal is in tune with the reference signal (column 16, line 52 through column 17, line 15). The reference channel and target channel can be considered “in tune” when the target channel “sounds” about the same as the reference channel at the discretion of the patient.

Regarding claims 25 and 26, Faltys et al. discloses a means for generating a probe signal that has a known tonal or speech sound relationship with the reference

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signal (column 17, line 15 through column 18, line 23). The argument against claims 25 and 26 is equivalent to that applied to claims 17-20 above.

It is noted that the “means for” language contained in claims 21-26 constitute an invocation of 35 U.S.C. 112, 6th paragraph.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 4-6 and 22 are rejected under 35 U.S.C. 103(a) as being obvious over Crosby et al. in view of Applicant's Admission of Prior Art (hereinafter referred to as Admission).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and

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reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Regarding claims 4 and 22, Crosby et al discloses the invention substantially as claimed, but does not expressly disclose the use of current steering to shift the location where the probe or reference signal is applied. Admission teaches that it is well known in the art to use current steering to effectively apply a stimulus current at an almost infinite number of locations within the cochlea (paragraph [7]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Faltys et al. with a current steering capability to provide the Faltys et al. system with the same means for applying a stimulus current to an almost infinite number of locations within the cochlea (motivation to combine provided by Applicant, paragraph [7]).

Regarding claims 5 and 6, determining which signal is defined as the probe signal and which is defined as the reference signal, and consequently whether the probe or reference signal is held constant while the other is shifted through current steering is clearly a matter of arbitrary design choice, and does not patentably distinguish over the prior art.

8. Claims 4-6 and 22 are rejected under 35 U.S.C. 103(a) as being obvious over Faltys et al. in view of Admission.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Regarding claims 4 and 22, Faltys et al. discloses the invention substantially as claimed, but does not expressly disclose the use of current steering to shift the location where the probe or reference signal is applied. Admission teaches that it is well known in the art to use current steering to effectively apply a stimulus current at an almost infinite number of locations within the cochlea (paragraph [7]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Faltys et al. with a current steering capability to provide the Faltys et al. system with the same means for applying a stimulus current to an almost infinite

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number of locations within the cochlea (motivation to combine provided by Applicant, paragraph [7]).

Regarding claims 5 and 6, determining which signal is defined as the probe signal and which is defined as the reference signal, and consequently whether the probe or reference signal is held constant while the other is shifted through current steering is clearly a matter of arbitrary design choice, and does not patentably distinguish over the prior art.

Allowable Subject Matter

9. Claims 7-9, 16, and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

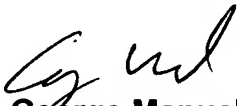
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

19 June 2006


George Manuel
Primary Examiner